DEC - 2 2003

K032968

SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

A. Submitted By:

Mattioli Engineering Corporation
7918 Jones Branch Drive
Suite 600
McLean, VA 22102

Tel: 703-312-6000
Fax: 703-243-9139

Contact Person: Ms. Linda Ferri
At address above

B. Device Trade Name: TRANSDERM IONTO System
Common Name: Iontophoresis Device
Classification Name: Device, Iontophoresis, Specific Uses

C. Predicate Devices:

Manufacturer	Product Name	510(k) No.
Life-Tech, Inc.	Microphor®	K913601
Life-Tech, Inc.	Iontophor® II	K863166

II. DEVICE DESCRIPTION

The TRANSDERM IONTO System consists of a probe, power supply/support, and a disposable drug delivery cap electrode.

Electrical pulses are produced by an electronic pulse generator that is able to generate bursts of pulses that are applied to the skin through electrodes applied to a plastic plate (the applicator). The design of the device provides one channel output.

The TRANSDERM IONTO System requires a DC supply of 9 V, 1.0 A max. This power source is supplied by, the TRANS-BASE module which is connected to mains through a removable supply cord and is equipped with a proper connector receptacle to fit the connector male mounted on TRANSDERM IONTO probe supply cable. The TRANS-BASE is equipped with a 15 w AC-DC switch mode power module.

The drug delivery cap electrode is adhered to the patient's skin and then saturated with ionic solution. Once the drug delivery cap electrode is affixed to the

patient's skin, the TRANSDERM IONTO probe's applicator head can be attached to the internal side of the drug delivery cap electrode.

III. INDICATIONS FOR USE

The TRANSDERM IONTO System is a powered iontophoresis drug delivery system that is indicated for the local administration of ionic drug solutions into the body for medical purposes and can be used as an alternative to injections.

IV. TECHNOLOGICAL COMPARISON

The TRANSDERM IONTO System, Microphor® (K913601), and Iontophor® II (K863166) have similar indications for use and overall function and perform in a similar manner with respect to iontophoretic drug delivery. Performance testing supports that there is no significant difference between the TRANSDERM IONTO System and the Iontophor® II. The TRANSDERM IONTO System utilizes a plastic plate containing electrodes and an adhesive drug delivery cap electrode to administer the ionic solution to the patient rather than the lead wires and adhesive electrodes of the Microphor® and Iontophor® II.

V. TESTING

Performance testing and the applicable IEC 60601-1 standards testing was performed.

VI. CONCLUSIONS

The TRANSDERM IONTO System is substantially equivalent to the legally marketed iontophoretic devices in intended use and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 2003

Mattioli Engineering Corporation
C/o Ms. Melissa Mahall
Bio-Reg Associates, Inc.
11800 Baltimore Avenue, Suite 105
Beltsville, Maryland 20705

Re: K032968
Trade/Device Name: TRANSDERM IONTO System
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: November 20, 2003
Received: November 24, 2003

Dear Ms. Mahall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the device as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(301) 594-1296

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594 – 4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K032968

Device Name: TRANSDERM IONTO System

Sponsor Name: Mattioli Engineering Corporation

Indications for Use:

The TRANSDERM IONTO System is a powered iontophoresis drug delivery system that is indicated for the local administration of ionic drug solutions into the body for medical purposes and can be used as an alternative to injections.

Prescription Use ☒ (21 CFR 801 Subpart D) And/Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milkman

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032968